Generic Name:
Naloxone hydrochloride nasal spray
Trade Name:
Narcan
Company:
Adapt Pharma
Notes:

FDA has approved naloxone hydrochloride as a nasal spray under the trade name Narcan. It is the first FDA-approved nasal spray version of naloxone, a life-saving medication that can stop or reverse the effects of an opioid overdose.

Until this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector. Many first responders and primary caregivers, however, feel a nasal spray formulation of naloxone is easier to deliver and eliminates the risk of a contaminated needle stick. As a result, there has been widespread use of unapproved naloxone kits that combine an injectable formulation of naloxone with an atomizer that can deliver naloxone nasally. Now, people have access to an FDA-approved product for which the drug and its delivery device have met the FDA?s high standards for safety, efficacy and quality.

Narcan nasal spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back and can be repeated if necessary.

However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan nasal spray should seek further immediate medical attention on the patient?s behalf.

The FDA granted fast-track designation and priority review for Narcan nasal spray. Narcan is being approved in less than 4 months, significantly ahead of the product?s prescription drug user fee goal date of January 20, 2016.

In clinical trials conducted to support the approval of Narcan nasal spray, administering the drug in one nostril delivered approximately the same levels or higher of naloxone as a single dose of an FDA-approved naloxone intramuscular injection, and achieved these levels in approximately the same time frame.

The National Institute on Drug Abuse (NIDA) played a critical role in the development of Narcan nasal spray as well, forming a public?private partnership by designing and conducting the clinical trials required to determine that the intranasal formulation delivered naloxone as quickly and as effectively as an injection. NIDA then worked with its private sector partners to obtain FDA approval.

Use of Narcan nasal spray in patients who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate, fever, runny nose,

sneezing, goose bumps, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure.

Medication Monitor Categories:

Supplemental Approvals
